DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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October 29, 2015

Pentax of America, Inc.
Mr. Krishna Govindarajan
Senior Manager, Regulatory Affairs
3 Paragon Drive
Montvale, NJ 07645

Re: K143727
Trade/Device Name: Pentax Medical EKP-i5010 Video Processor With EB Family
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (Flexible Or Rigid) And Accessories
Regulatory Class: Class II
Product Code: EOQ, PEA
Dated: September 28, 2015
Received: September 29, 2015

Dear Mr. Govindarajan,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Eric A. Mann -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K143727

Device Name
PENTAX Medical EPK-i5010 Video Processor with EB Family

Indications for Use *(Describe)*
The PENTAX Medical EPK-i5010 Video Processor is intended to be used with the PENTAX camera heads, endoscopes, light sources, monitors and other ancillary equipments for bronchoscopic diagnosis, treatment and video observation. The PENTAX Medical EPK-i5010 includes PENTAX i-Scan™, a digital, post-processing imaging enhancement technology. i-Scan is intended to be used as an optional adjunct following traditional white light endoscopy and is not intended to replace histopathological sampling. i-Scan is compatible with PENTAX k-series and i-series video bronchoscopes.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

The following summary is provided in accordance with 21 CFR 807.92:

I. SUBMITTER

PENTAX of America, Inc.,
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3 Paragon Drive
Montvale, New Jersey 07645-1782

Phone: 201-251-2300 x 2125
Fax: 201-799-4117

Contact Person: Krishna Govindarajan
Date Prepared: October 28, 2015

II. DEVICE

Name of Device:	PENTAX Medical EPK-i5010 Video Processor with EB Family
Common or Usual Name:	Endoscopic Video Processor and Light Source
Classification Name:	Endoscopic video imaging system/component,
Classification Name:	Bronchoscopes (Flexible or rigid) and accessories (21 CFR Part 874.4680)
Regulatory Class:	Class II
Product Code:	EOQ and PEA

III. PREDICATE DEVICE

The OLYMPUS EVIS EXERA III Video System CV‐190 Video System Center and CLV‐190, Xenon Light Source (K121959) is the primary predicate for this submission.

The PENTAX EPK-i5010 Video Processor (K122470; dated April 22, 2013) is the reference device for this submission.
This reference device has not been subject to a design-related recall.

IV. DEVICE DESCRIPTION

The PENTAX EPK-i5010 video processor consists of a video system, integrated light source, monitor, and ancillary equipment. This processor when connected to a compatible EB family bronchoscope is intended for endoscopic diagnostic, treatment and video observation.

The PENTAX i-Scan technology is a digital filter-based image enhancement technique with three modes, i-Scan 1, 2 and 3. i-Scan 1 enhances image topography and edges and i-Scan 2 and 3 enhances the color tone of the image by dissecting and recombining the individual red, green and blue (RGB) components of a white light image.

PENTAX i-Scan™ modes 1, 2, and 3, are intended to give the user an enhanced view of the texture of the mucosal surface and blood vessels. i-Scan 1 provides the user with a view that sharpens surface vessels and enhances surface texture of the mucosa. i-Scan 2 provides the user with increased visibility of blood vessels while also providing the same enhancements to the mucosa achieved in i-Scan 1. i-Scan 3 provides the user with increased visibility of blood vessels including dimly illuminated far-field regions while also providing the same enhancement to the mucosa achieved in i-Scan 1. The user can select either white light image or i-Scan modes by pressing a pre-programmed button on the scope, by using a pre-programmed foot pedal or by pressing a keyboard button. i-Scan is intended to be used as an optional adjunct following traditional white light endoscopy and is not intended to replace histopathological sampling.

White light is captured from a 300 Watt xenon lamp housed in the EPK-i5010 video processor. All visualization is done with the white light mode first. White light (BGR) illuminates the tissue and transfers the captured light through the video scope or a charged coupled device (CCD). Note that the white light visualization mode is always used first by the physician. The modification of the combination of RGB components for each pixel occurs when the i-Scan function is turned on in the EPK-i5010 video processor. The resulting i-Scan image is then displayed on the observation monitor.

The table below are the list of accessories and compatible devices that are used with the EPK-i5010 Video Processor.

Table 1: List of Accessories

Accessories Name	Intended Use	Model Number
PENTAX Condenser Earth Cable	Condenser earth cable OL-Z4 is intended to reduce high- frequency noise which is generated during high- frequency electro cautery device use together with Pentax endoscopes.	OL-Z4
PENTAX Foot Switch	Foot Switch OS-A61 is used to remotely control processor functions.	OS-A61
PENTAX Keyboard	Keyboard OS-A79 is used as an input device for the video processor.	OS-A79
PENTAX White Balance Adjuster	White Balance Adjuster OS- A43H is a white tube used as the object of white balance feature.	OS-A43H

Table 2: List of Compatible Devices

Compatible Devices	Manufacturer	Model Name
Printer	Sony Corporation	UP-55MD
	Sony Corporation	UP-21MD
	Sony Corporation	UP-D23MD
	Sony Corporation	UP-D23MDA
USB Flash Memory	SanDisk	SDCZ6-1024-A10
LCD Monitor	NDS Surgical Imaging	Radiance 19

The EPKi-5010 is compatible with PENTAX k-series and i-series video bronchoscopes.

V. INDICATIONS FOR USE

The PENTAX Medical EPK-i5010 Video Processor is intended to be used with the PENTAX camera heads, endoscopes, light sources, monitors and other ancillary equipment for bronchoscopic diagnosis, treatment and video observation.

The PENTAX Medical EPK-i5010 includes PENTAX i-Scan™, a digital, post-processing imaging enhancement technology. i-Scan is intended to be used as an optional adjunct following traditional white light endoscopy and is not intended to replace histopathological sampling. i-Scan is compatible with PENTAX k-series and i-series video bronchoscopes.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The PENTAX Medical EPK-i5010 Video Processor with EB Family (subject device) has the same intended use and fundamental operating principle as the OLYMPUS EVIS EXERA III Video System CV‑190 Video System Center and CLV‑190, Xenon Light Source (K121959) (primary predicate device). Both devices also have the same indications for use; namely, for use in bronchoscopic diagnosis, treatment and video observation in the pulmonary anatomy. The devices differ slightly with regard to design and technological characteristics. Performance data, specifically optical bench and animal testing, is provided to support substantial equivalence of the devices.

The PENTAX Medical EPK-i5010 Video Processor with EB Family (subject device) has the same intended use, design, fundamental operating principle, and scientific technology, including the PENTAX i-Scan image enhancement technology, compared to the commercially available PENTAX EPK-i5010 Video Processor (reference device). There were minor changes made to the EPK-i5010 Video Processor with EB Family to address the requirements of the 3rd edition of IEC 60601. However, these changes did not affect the

final product specification and did not raise any questions of safety or effectiveness. The only substantive difference between the subject and primary predicate device is in use of the device in different anatomical locations. The subject device is used for bronchoscopic diagnosis, treatment and video observation in the pulmonary anatomy and the predicate device is used for gastrointestinal endoscopic diagnosis, treatment and video observation in the upper and lower gastrointestinal anatomical location.

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Electrical Safety and electromagnetic compatibility (EMC)
The acceptable level of Electromagnetic Compatibility (EMC) and Electrical Safety (ES) for the PENTAX Medical EPK-i5010 Video Processor with EB Family was confirmed by testing in accordance with the following standards:

1. IEC 60601-1:2005+A1:2012, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
2. IEC 60601-1-2:Edition 3:2007, Medical electrical equipment- Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
3. IEC 60601-1-6 Edition 3.0:2010, Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
4. IEC 60601-2-18 Edition 3.0:2009: , Medical electrical equipment- Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment

Software Verification and Validation Testing
Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software is classified as CLASS B under the Software Safety Classification per IEC 62304:2006, Medical device software- Software life cycle processes) and the software level of concern is "Moderate" based on the FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."

All testing of the software was conducted in compliance with the following standards:

1. ISO 14971 Second Edition:2007, Medical devices -Application of risk management to medical devices
2. IEC 62304 First Edition:2006, Medical device software- Software life cycle processes
3. IEC 62471 First Edition:2006, Photobiological safety of lamps and lamp systems

Optical Performance Testing (Bench and Animal non-clinical testing)

Animal Study
A library of images [white light endoscopic (WLE), PENTAX i-Scan™, and Olympus Narrow Band Imaging (NBI)] were obtained from the porcine pulmonary mucosa. The images were used for image evaluation and quantitative data analysis.

Bench Testing
i-Scan and Artifact Analysis were performed with the images from the porcine pulmonary location that were gathered using two PENTAX bronchoscopes, one high definition and one standard definition, along with an Olympus bronchoscope. In addition, PENTAX and Olympus bronchoscopes were compared and optical bench testing was conducted to evaluate the effects of processing features and demonstrate the equivalence of the distortion, resolution and color performance of the subject compared to the predicate.

The animal and optical bench test image data gathered with bronchoscopes establish the equivalence of the subject and predicate device.

VIII. CONCLUSIONS

The data submitted support the safety of the device and the hardware and software verification and validation demonstrate that the PENTAX Medical EPK-i5010 Video Processor performs as intended in the specified use conditions. The optical data analysis demonstrate that the PENTAX Medical EPK-i5010 Video Processor performs comparably to the predicate device that is currently marketed for the same indication for use.